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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,181

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Rijkje Cornelia Sprong

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THE WEBB LAW FIRM, P.C.  
700 KOPPERS BUILDING  
436 SEVENTH AVENUE  
PITTSBURGH, PA 15219

EXAMINER

ROMEO, DAVID S

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/589,181	<b>Applicant(s)</b> SPRONG ET AL.	
	<b>Examiner</b> David S. Romeo	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 29-42 is/are pending in the application.
- 4a) Of the above claim(s) 31-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29,30 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 29-42 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0807</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 29–42 are pending.

#### *Election/Restrictions*

Applicant's election with traverse of the prevent and/or reduce hangover species in the

5 reply filed on 08/24/2009 is acknowledged. The traversal is on the ground(s) that:

...there is unity of invention with regard to Species I (claim 30), Species II (claim 31), Species III (claim 32), Species V (claim 34), and Species X (claim 39). Specifically, Applicants assert that each of the conditions treated in Species I, Species II, Species III, Species V, and Species X, are conditions associated with  
10 liver function and are supported by thiol redox equilibrium (see the specification, e.g., par. [0003], par. [0026] and par. [0017] and Example 8). Therefore, because each of these conditions are associated with liver function and are supported by thiol redox equilibrium there is unity of invention with regard to Species I, Species II, Species III, Species V, and Species X.

15 ...no serious burden exists on the Examiner.

This is not found persuasive because: Assuming for the sake of argument that each of the conditions treated in claims 30–32, 34 and 39 are associated with liver function and are  
20 supported by thiol redox equilibrium, unity of invention would still be lacking because unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior  
25 art. Whether or not any particular technical feature makes a “contribution” over the prior art, and therefore constitutes a “special technical feature,” is considered with respect to novelty and inventive step.

Art Unit: 1647

Applicants' certainly did not invent the conditions being treated. Therefore, these conditions cannot be considered to define a contribution over the prior art. The special technical feature among the claimed inventions is a mixture of peptides comprising at least 6.5% wt cysteine. However, Mallee (U. S. Publication No. 20020090670) discloses a mixture of peptides having a cysteine content between 7-20 w/w % and the use of the preparation as active component in a medicament, especially for the treatment of conditions mediated by oxidative damage and for the elevation of cellular glutathion levels in the human or animal body. See the Abstract. Furthermore, the claimed invention is obvious, as indicated in the rejection below. Therefore, the special technical feature among the claimed inventions cannot be considered novel or cannot be considered to involve an inventive concept. Therefore, the inventions do not fulfill the requirements for unity of invention.

Regarding "serious burden", search burden is not germane to the determination of lack of unity.

The requirement is still deemed proper and is therefore made FINAL.

Claims 31–41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 08/24/2009.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 29, 30 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou (Exp Biol Med (Maywood). 2002 Mar;227(3):214-22) in view of Mallee (U. S. Publication No. 20020090670).

5           According to Zhou:

Antioxidants are likely potential pharmaceutical agents for the treatment of alcoholic liver disease (Abstract).

10           There is increasing evidence that oxidative stress plays an important etiologic role in the development of alcoholic liver disease. Alcohol administration has been found to cause accumulation of reactive oxygen species, including superoxide, hydroxyl radical, and hydrogen peroxide. Reactive oxygen species, in turn, cause lipid peroxidation of cellular membranes, and protein and DNA oxidation, which results in hepatocyte injury. See page 214, right column, full paragraph 2.

15           One of the most prominent defense systems in the liver is the presence of reduced glutathione (GSH). Most studies have reported that acute ethanol administration decreases hepatic GSH content. The decrease in GSH has been related to an enhanced oxidation of GSH to oxidized glutathione (GSSG) as a consequence of increased generation of reactive oxygen species. Restoration of GSH has been shown to inhibit ethanol-induced liver injury. See page 214, right column, full paragraph 3. These results suggest that increasing hepatic antioxidant defense is likely a potential therapy for alcoholic liver disease. See page 214, right column, full paragraph 3.

25           Therefore, the examiner concludes that a subject that has consumed alcohol is a subject in need of restoring thiol homeostasis. Zhou does not teach a method for restoring thiol homeostasis in a subject in need thereof, comprising administering to said subject an effective amount of a mixture of peptides comprising at least 6.5% wt cysteine, wherein said mixture of peptides is  
30           administered to prevent and/or reduce effects of alcohol consumption in a subject in need thereof.

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Mallee discloses a preparation comprising cysteine-rich peptides, comprising 7-20 w/w % cysteine (claim 16) and its use in a medicament for the treatment of conditions mediated by oxidative damage (claim 20) and for the elevation of cellular glutathion levels in the human or animal body (claim 21). Glutathion is therefore regarded as an important compound against oxidative stress related diseases (paragraph [0004]). Mallee does not teach a method for restoring thiol homeostasis in a subject in need thereof, comprising administering to said subject an effective amount of a mixture of peptides comprising at least 6.5% wt cysteine, wherein said mixture of peptides is administered to prevent and/or reduce effects of alcohol consumption in a subject in need thereof.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to restore GSH to inhibit ethanol-induced liver injury, as taught by Zhou, and to modify that teaching by administering a preparation comprising cysteine-rich peptides, comprising 7-20 w/w % cysteine, as taught by Mallee, in order to prevent and/or reduce effects of alcohol consumption with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because there is increasing evidence that oxidative stress plays an important etiologic role in the development of alcoholic liver disease, acute ethanol administration decreases hepatic GSH content, restoration of GSH has been shown to inhibit ethanol-induced liver injury, glutathion is regarded as an important compound against oxidative stress related diseases, a preparation comprising cysteine-rich peptides, comprising 7-20 w/w % cysteine treats conditions mediated by oxidative damage and elevates cellular glutathion levels.

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Claim 42 is drafted using a product-by-process format. The recitation of the process in claim 42 is not viewed as positively limiting the product absent a showing that the process imparts a novel or unexpected property to the product, as it is assumed that equivalent products are obtainable by multiple routes.

5 The invention is prima facie obvious over the prior art.

***Conclusion***

No claims are allowable.

10 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, MANJUNATH RAO, CAN BE REACHED AT (571)272-0939.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

15 CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

20 ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE [HTTP://PAIR-DIRECT.USPTO.GOV](http://PAIR-DIRECT.USPTO.GOV). CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

/DAVID S ROMEO/  
PRIMARY EXAMINER, ART UNIT 1647

25  
DSR  
SEPTEMBER 8, 2009